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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/677,752	10/03/00	JACKSON	W 7969-087

EXAMINER

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ART UNIT	PAPER NUMBER
1645	4

DATE MAILED: 03/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/677,752	JACKSON, W. JAMES	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-72* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Detailed Action

Election/Restriction

1. Claims 1-72 are noted as reciting improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F. 2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within Markush group (1) share a common unity and (2) share substantial structural feature disclosed as being essential to that utility.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-7, 15-24, 31-32, 41, 57-59 are drawn to an isolated PMPE polypeptide of *Chlamydia spp* in Class 530, Subclass 350.

Group II. Claims 1-7, 15-24, 31-32, 41, 57-59 are drawn to an isolated PMPI polypeptide of *Chlamydia spp* in Class 530, Subclass 350.

Group III. Claims 11-14, 30 are drawn to an antibody or antigen-binding fragment thereof that specifically binds PMPE and vaccine in Class 530, Subclass 387.1.

Group IV. Claims 11-14, 30 are drawn to an antibody or antigen-binding fragment thereof that specifically binds PMPI and vaccine in Class 530, Subclass 387.1.

Group V. Claims 8-10, 25-29, 31-32 are drawn to an isolated fusion polypeptide comprising at least two peptides and at least two peptides each consisting of an amino acid sequence different from PMPE and PMPI and vaccine in Class 435, Subclass 69.7.

Group VI. Claims 33-41,48, 50-56 are drawn to a nucleic acid molecule comprising a nucleotide sequence encoding a PMPE polypeptide in Class 536, Subclass 23.7.

Group VII. Claims 33-41,49, 50-56 are drawn to a nucleic acid molecule comprising a nucleotide sequence encoding a PMPI polypeptide in Class 536, Subclass 23.7.

Group VIII. Claims 42-44, 46-47 are drawn to a method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of PMPE polypeptide in Class 424, Subclass 185.1.

Group IX. Claims 42-44, 46-47 are drawn to a method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of PMPI polypeptide in Class 424, Subclass 185.1.

Group X. Claim 44 and 47 is drawn to a method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of a isolated fusion protein in Class 424, Subclass 185.1.

Group XI. Claims 45 and 47 are drawn to a method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of nucleic acid molecule encoding PMPE in Class 514, Subclass 44.

Group XII. Claims 45 and 47 are drawn to a method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of nucleic acid molecule encoding PMPI in Class 514, Subclass 44.

Group XIII. Claims 47 are drawn to a method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of an antibody to PMPE in Class 514, Subclass 44.

Group XIV. Claims 47 are drawn to a method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of antibody to PMPI in Class 514, Subclass 44.

Group XV. Claims 60-62, 65, 67-68 are drawn to a method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with Chl*amydia* by administering to the subject an effective amount of PMPE polypeptide in Class 424, Subclass 190.1.

Group XVI. Claims 60-62, 65, 67-68 are drawn to a method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with Chl*amydia* by administering to the subject an effective amount of PMPI polypeptide in Class 424, Subclass 190.1.

Group XVII. Claims 63 and 68 are drawn to a method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with Chl*amydia* by administering to the subject an effective amount of antibody to PMPE polypeptide in Class 424, Subclass 190.1.

Group XVIII. Claims 63 and 68 are drawn to a method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with Chl*amydia* by administering to the subject an effective amount of antibody to PMPI polypeptide in Class 424, Subclass 190.1.

Group XIX. Claim 64 and 68 are drawn to a method of preventing, treating or ameliorating a disorder or disease associated with the infection of an animal with *Chlamydia* by administering to a subject an effective amount of an isolated fusion protein in Class 424, Subclass 190.1.

Group XX. Claims 66-68 are drawn to a method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with Chl*amydia* by administering to the subject an effective amount of nucleic acid molecule encoding PMPI polypeptide in Class 514 Subclass 44.

Group XXI. Claim 66-68 are drawn to a method of preventing, treating or ameliorating a disorder or disease associated with the infection of an animal with *Chlamydia* by administering to a subject an effective amount nucleic acid molecule encoding PMPI polypeptide in Class 514 Subclass 44.

Group XXII. Claim 69 is drawn to an antagonist which inhibits the activity of the PMPE polypeptide in Class 530, Subclass 300.

Group XXIII. Claim 69 is drawn to an antagonist which inhibits the activity of the PMPI polypeptide in Class 530, Subclass 300.

Group XIX. Claim 70 is drawn to an antagonist which inhibits expression in the nucleic acid molecule which encodes PMPE in Class 536, in Subclass 24.5.

Group XXV. Claim 70 is drawn to an antagonist which inhibits expression in the nucleic acid molecule which encodes PMPI in Class 536, in Subclass 24.5.

Group XXVI. Claim 71 is drawn to method of identifying compounds that interact with the PMPE polypeptide in Class 435, Subclass 7.1.

Group XXVII. Claim 71 is drawn to method of identifying compounds that interact with the PMPI polypeptide in Class 435, Subclass 7.1.

Group XXVIII Claim 72 is drawn to method of identifying compounds that interact with the nucleic acid molecule that encodes PMPE polypeptide in Class 435, Subclass

Group XXIX. Claim 72 is drawn to method of identifying compounds that interact with the nucleic acid molecule that encodes PMPI polypeptide in Class 435, Subclass 6.

3. Inventions I and II are related as products. Inventions I and II are drawn to a polypeptide molecule. They differ because they are drawn to structurally and functionally distinct proteins encoded by different genes. Invention I is drawn to PMPE which is encoded by the pmpE gene and Invention II is drawn to PMPI which encoded by the pmpI gene.

4. Inventions III and IV are related as products. Inventions III and IV are drawn to antibodies. They differ because they bind to structurally and functionally distinct proteins. Inventions III and IV are distinct from Inventions I and II, since they have an inherent affinity, avidity and specificity that a simple protein is not capable of expressing and are produced by different methods.

5. Inventions V and (X and XIX) are related as product and process of use. Inventions V is drawn to a fusion protein and vaccine. These inventions can be shown to be distinct if either or both of the following can be shown. (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP 806.05(h). Invention X is drawn to a method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of a isolated fusion protein. Invention XIX is drawn to a method of preventing, treating or ameliorating a disorder or disease associated with the infection of an animal with *Chlamydia* by administering to a subject an effective amount of an isolated fusion protein. In the instant case, the fusion protein of Invention V can be used in materially different methods as evidenced by distinct methods of Inventions X and XIX. Inventions X and XIX require different goals, method steps, reagents, have different parameters and have different final outcomes (ie. immune response vs. prevention from infection.) Invention V is different from I-IV because it is drawn to a fusion protein consisting of amino acid sequence different from the polypeptides PMPE and PMPI.

6. Inventions VI and VII are related as products. Inventions VI and VII are drawn to a nucleic acid molecule. They differ because they are drawn to structurally and functionally distinct proteins encoded by different genes. Inventions VI and VII are distinct from I-V because they are drawn to a nucleotide molecule which consists of

nucleic acids and Inventions I-II are drawn to polypeptides which consists of amino acids. Methods for making polypeptides are different from methods of making nucleotide molecules. Different reagents and parameters are required. Inventions VI and VII are distinct from Inventions III and IV because Inventions III and IV are drawn to antibodies. Antibodies have an inherent affinity, avidity and specificity that a nucleotide is not capable of expressing. Inventions VI and VII differ from V because is drawn to a fusion protein.

7. Inventions VIII and IX are related as methods. Inventions VIII and IX are drawn to a method of inducing an immunological response comprising administrating to the animal an immunogenic amount of a polypeptides . They differ because they are drawn to structurally and functionally distinct proteins. Inventions VIII and IX are distinct from I-VII because they are drawn to a method which requires the induction of an immunological response in an animal. Therefore, VIII and IX require additional reagents and parameters to induce an in vivo reaction.

8. Inventions XI and XII are related as methods. Inventions XI and XII are drawn to a method of producing an immune response in an animal comprising the administrating to the animal an immunogenic amount of nucleic acid molecule encoding PMPE or PMPI. They differ because they encode structurally and functionally distinct proteins. Inventions XI and XII differ from I-VII because they are drawn to a method which requires the induction of an immunological response in an animal. Inventions XI and XII

differ from VIII and XI because they are drawn to a nucleic acid molecule. Therefore, XI and XII require additional reagents and parameters to induce an in vivo reaction. Inventions XI and XII differ from Invention X because Invention X is drawn to a fusion protein.

9. Inventions XIII and XIV are related as methods. Inventions XIII and XIV are drawn to a method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of an antibody to a polypeptide. They differ because they are drawn to structurally and functionally distinct proteins. Inventions XIII and XIV are different from Invention I -VII because they are drawn to a method which requires the induction of an immunological response in an animal. Inventions XIII and XIV are distinct from Inventions VIII-XII because they are drawn to an antibody. Antibodies have an inherent affinity, avidity and specificity that a simple protein or nucleic acid molecules are not capable of expressing.

10. Inventions XV and XVI are related as methods. Inventions XV and XVI are drawn to a method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with Chl*amydia* by administering to the subject an effective amount of a polypeptide. They differ because they are drawn to structurally and functionally distinct proteins. Inventions XV and XVI are distinct from Inventions I-VII because they are drawn to a method which requires preventing, treating or ameliorating a disorder or disease. Inventions XV and XVI are distinct from Inventions

VIII-XII because they are drawn to a method which requires preventing, treating or ameliorating a disorder or disease verses a method of inducing an immunological response in an animal different reagents and parameters are required. Inventions XV and XVI are distinct from XIII and XIV because they are drawn to a polypeptide and XIII and XIV are drawn to antibodies. Antibodies have an inherent affinity, avidity and specificity that a simple protein are not capable of expressing.

11. Inventions XVII and XVIII are related as methods. Inventions XVII and XVIII are drawn to a method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with Chl*amydia* by administering to the subject an effective amount of an antibody to a polypeptide. They differ because they are drawn to structurally and functionally distinct proteins. Inventions XVII and XVIII are distinct from Inventions I-VII because they are drawn to a method which requires preventing, treating or ameliorating a disorder or disease. Inventions XVII and XVIII are distinct from Inventions VIII-XVI because they are drawn to a method which requires preventing, treating or ameliorating a disorder or disease using an antibody verses a method which requires inducing an immunological response in an animal, therefore, different reagents and parameters are required.

12. Inventions XX and XXI are related as methods. Inventions XVII and XVIII are drawn to a method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with Chl*amydia* by administering to the subject an

effective amount of a nucleic acid molecule encoding a polypeptide. They differ because they are drawn to structurally and functionally distinct proteins. Inventions XX and XXI are distinct from Inventions I-VII because they are drawn to a method which requires preventing, treating or ameliorating a disorder or disease. Inventions XX and XXI are distinct from Inventions VIII-XIX because they are drawn to a method which requires preventing, treating or ameliorating a disorder or disease using a nucleic molecule that encodes a polypeptide verses a method of inducing an immunological response in an animal, therefore, different reagents and parameters are required.

13. Inventions XXII and XXIII are drawn to an antagonist which inhibits the activity of a polypeptide. Inventions XXII and XIXIII differ because they are drawn structurally and functionally distinct proteins. Inventions XXII and XXIII differ from I-XI because they have added features that allow them to interact with the polypeptides in a manner so they inhibit the biological activity of the polypeptide.

14. Inventions XXIV and XXV are drawn to an antagonist which inhibits expression in the nucleic acid molecule which encodes a protein. Inventions XXIV and XXV differ because they encode structurally and functionally distinct proteins. Inventions XXIV and XXIV differ from I-XXIII because they have added features that allow them to interact with the nucleic acid which encodes a protein in a manner so they inhibit expression of the nucleic acid molecule.

15. Inventions XXVI and XXVII are drawn to a method of identifying compounds that interact with a polypeptide. They differ because they are drawn to structurally and functionally distinct proteins. Inventions XXVI and XXVI differ from I-XXIII because they require additional biological reagents and parameters to test compounds that react with the polypeptide.

16. Inventions XXVIII and XXIX are drawn to a method of identifying compounds that interact with the nucleic acid molecule that encodes a polypeptide. Inventions XXVIII and XXIX differ because they encode structurally and functionally distinct proteins. Inventions XXVIII and XXIX differ from I-XXV because they require additional biological reagents and parameters to test compounds that react with the polypeptide. Inventions XXVIII and XXIX differ from Inventions XXVI and XXVII because they interact with the nucleic acid molecule that encodes the polypeptide and not the protein directly.

17. Groups I and (VIII, XV and XXVI) or Groups II and (IX, XVI and XXVII) are product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process of using that product (MPEP 806.05(h). In the instant case the inventions of Group I or II may be used for a number of different processes that are very much unrelated. For example, the polypeptides of Groups I or II can be used as antigens to produce antibodies.

18. Groups VI and (XI, XX and XXVIII) or Groups VII and (XII, XXI and XXIX) are product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process of using that product (MPEP 806.05(h). In the instant case the inventions of Group VI or VII may be used for a number of different processes that are very much unrelated. For example, the nucleic acid of Group VI or VII can be used as DNA probes or can be incorporated into plasmids.

19. Groups III and (XIII and XVII) or Groups IV and (XIV and XVIII) are product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process of using that product (MPEP 806.05(h). In the instant case the inventions of Group III or IV may be used for a number of different processes that are very much unrelated. For example, the antibodies of Group III or IV can be used to make diagnostic reagents. These reagents can be used in other processes such as affinity chromatography.

20. Restriction to one of the following inventions is required under 35 U.S.C. 121: The inventions are distinct, each from the other because of the following reasons:

Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, in the absence of restriction it would place an undue search and examination burden on the examiner.

21. Applicant is advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

22. Applicant is reminded that upon that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

23. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 305-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Patent Examiner
March 28, 2001

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER